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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/876,143	06/06/2001	Ken Eilertsen	028040-0202	6701

30542 7590 05/14/2003

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EXAMINER

BRUSCA, JOHN S

ART UNIT PAPER NUMBER

1631

DATE MAILED: 05/14/2003

13

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/876,143

Applicant(s)

EILERTSEN ET AL.

Examiner

John S. Brusca

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-60 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 1-60 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). ____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____ 6) ☐ Other: ____

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
 1. Claims 1 and 2, drawn to a polynucleotide, classified in class 536, subclass 23.1.
 2. Claims 3-14 and 40-42, drawn to a polynucleotide sequence database, classified in class 365, subclass 94.
 3. Claims 15-20, drawn to a method of screening polynucleotides, classified in class 435, subclass 6.
 4. Claims 21-24, drawn to a method of making a transgenic animal, classified in class 800, subclass 21.
 5. Claims 25-34, drawn to a method of assaying developmental competence of cells, classified in class 435, subclass 7.21.
 6. Claims 35-39, drawn to polynucleotide arrays, classified in class 536, subclass 24.31.
 7. Claims 43-45, drawn to a method of screening polynucleotide sequences derived from stem cells, classified in class 435, subclass 6.
 8. Claims 46-48, 51, 55, 56, 58, and 59, drawn to a method of screening embryos, classified in class 435, subclass 7.21.
 9. Claims 49 and 50, drawn to a therapeutic method comprising inducing totipotency, classified in class 514, subclass 1.

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10. Claims 52 and 53, drawn to a method of preventing pregnancy, classified in class 514, subclass 1.
11. Claim 54, drawn to a therapeutic method comprising inhibiting totipotency, classified in class 514, subclass 1.
12. Claim 57, drawn to a therapeutic method comprising induction of cell development, classified in class 514, subclass 1.
13. Claim 60, drawn to a therapeutic method comprising inhibition of cell development, classified in class 514, subclass 1.

The inventions are distinct, each from the other because of the following reasons:

2. Inventions 1, 2, and 6 are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are drawn to different compositions that can be used in different methods.
3. Inventions 3-5, and 7-13 are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are drawn to different methods that comprise different steps and produce different results.
4. Inventions 1 and 3 are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the method of identifying ESTs of invention 3 does not make or use the ESTs of invention 1.

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5. Inventions 1 and inventions 4, 5, and 7-13 are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01).

In the instant case the methods of inventions 4, 5, and 7-13 do not use or make the ESTs of invention 1.

6. Inventions 3 and 2 are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the ESTs of invention 2 could be identified by comparison of unaltered cells.

7. Inventions 2 and inventions 4, 5, and 7-13 are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the methods of inventions 4, 4, and 7-13 do not make or use the EST database of invention 2.

8. Inventions 6 and inventions 3-5, and 7-13 are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the methods of inventions 7-13 do not make or use the arrays of invention 6.

9. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

10. Because these inventions are distinct for the reasons given above and the search required for Groups 3 and 7, Groups 5 and 8, and Groups 9-13, each classified identically, is not coextensive, restriction for examination purposes as indicated is proper.

Sequence Election Requirement Applicable to All Groups

11. In addition, Groups 1, 2, and 6 detailed above read on patentably distinct sequences. Each sequence is patentably distinct because they are unrelated sequences, and a further restriction is applied to each Group. For Group 1 the applicants must elect a single polynucleotide sequence. For Groups 2 and 6 the applicants must elect a single combination of polynucleotide sequences. Examination will be restricted to only the elected sequence. Groups 1, 2, and 6 are generic to a plurality of disclosed patentably distinct species comprising EST polynucleotides. Applicant is required under 35 U.S.C. 121 to elect polynucleotide sequences as described above, even though this requirement is traversed.

Species Election

12. This application contains claims directed to the following patentably distinct species of the claimed invention: In invention 8 the species are the cell lines listed in claim 47, in invention 9 the species are the target cells listed in claim 50, and in invention 10 the species are the target cells listed in claim 53.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, in invention 8 claims 46, 48, 51, 55, 56, 58, and 59 are generic, in invention 9 claim 49 is generic, and in invention 10 claim 52 is generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

13. A telephone call was made to Michael Whittaker on 26 February 2003 to request an oral election to the above restriction requirement, but did not result in an election being made.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

14. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the

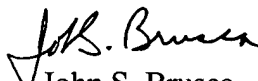
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application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to John S. Brusca whose telephone number is 703 308-4231. The examiner can normally be reached on M-F 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on 703 308-4025. The fax phone numbers for the organization where this application or proceeding is assigned are 703 746-5137 for regular communications and 703 746-5137 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703 308-0196.


John S. Brusca
Primary Examiner
Art Unit 1631

jsb
May 12, 2003